



*IN THE UNITED STATES PATENT AND TRADEMARK OFFICE*

Applicant: Keiko MATSUMOTO et al.  
Title: METHOD OF MULTIQUANTIFICATION FOR CHOLESTEROL  
OF LOW-DENSITY LIPOPROTEIN  
Appl. No.: 10/594,898  
International Filing Date: 03/30/2005  
371(c) Date: 9/29/2006  
Examiner: Unassigned  
Art Unit: Unassigned  
Confirmation Number: Unassigned

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.56**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56.

A copy of each non-U.S. patent document and each non-patent document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

**TIMING OF THE DISCLOSURE**

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

**RELEVANCE OF EACH DOCUMENT**

Any document listed on the attached PTO/SB/08 was cited as being relevant during the prosecution of the corresponding International application. A copy of the International Search Report is attached setting forth the portion of each document considered relevant by the examiner.

An English language summary of JP 2001-124780 & JP 2001-224397 are submitted herewith.

US Patent No. 6 057 118 corresponds to WO 97/45553 both of which are submitted herewith.

US Patent No. 6 194 164 corresponds to WO 98/47005 both of which are submitted herewith.

EP 1114870 corresponds to WO 00/017388 both of which are submitted herewith.

English translations of “LDL Cholesterol to So-Cholesterol no Multi Teiryoho”; “Koshikessho LDL-Cholesterol no Chokusetsu Sokuteiho”; and “Atarashii LDL Cholesterol Cokusetsuho Shiyaku (LDL-EX) no Kaihatsu” are submitted herewith.

An English-language counterpart of the foreign-language documents has been provided where readily available. The absence of a full translation or an English-language counterpart document does not relieve the PTO from its duty to consider any submitted document (37 CFR §1.98 and MPEP§609).

Applicants respectfully request that each listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

Although Applicant believes that no fee is required for this Request, the Commissioner is hereby authorized to charge any additional fees which may be required for this Request to Deposit Account No. 19-0741.

Respectfully submitted,

Date 28 December 2008

By S. A. Bent

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Substitute for form 1449/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Application Number	10/594,898
Date Submitted: December 28, 2006		Filing Date	3/30/2005
(use as many sheets as necessary)		First Named Inventor	Keiko MATSUMOTO
		Art Unit	Unassigned
		Examiner Name	Unassigned
		Attorney Docket Number	081356-0267

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	A1	5 925 534 A	7/20/1999	WAKO PURE CHEMICAL INDUSTRIES LTD.	
	A2	6 057 118 A	5/2/2000	DAIICHI PURE CHEMICALS CO., LTD.	
	A3	6 194 164 B1	2/27/2001	DENKA SEIKEN CO., LTD.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Documents	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				
	A4	WO 00/73797 A2	12/7/2000	THE GOVERNMENT OF THE UNITED STATES OF AMERICA as represented by THE SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES		
	A5	JP 2001-124780	5/11/2001	SHOWA DENKO KK		
	A6	WO 97/45553 A1	12/4/1997	Daiichi Pure Chemicals Co., Ltd.		
	A7	WO 98/47005 A1	10/22/1998	Denka Seiken Kabushiki Kaisha		
	A8	JP 2001-224397	8/21/2001	DENKA SEIKEN CO LTD.		
	A9	WO 00/017388 A1	3/3/2000	KYOWA MEDEX CO., LTD.		
	A10	EP 1 114 870 A1	7/11/2001	KYOWA MEDEX CO., LTD.		

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.		
		T <sup>6</sup>		
	A11	Hiroshi MATSUI, "LDL-Cholesterol to So-Cholesterol no Multi Teiryoho", Japanese Journal of Clinical Laboratory Automation, August 2003, 28(4), page 380.		
	A12	Takashi KANNO, "Koshikessho LDL-Cholesterol no Chokusetsu Sokuteiho", Current Therapy, 16(1), 1998, pp. 146-150.		
	A13	Takashi MATSUI, "Atarashii LDL Cholesterol Chokusetsuho Shiyaku (LDL-EX) no. Kaihatsu", Seibutsu Shiryo Bunseki, 21(5), 1998, pp. 361-366.		

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.